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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER CROW, ROBERT THOMAS	
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			1634	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/526,139

**Applicant(s)**

FUJITA, GORO

**Examiner**

Robert T. Crow

**Art Unit**

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 7-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**FINAL ACTION**

***Status of the Claims***

1. This action is in response to papers filed 12 March 2009 in which claims 1-2 were amended, no claims were canceled, and no new claims were added. All of the amendments have been thoroughly reviewed and entered.

The previous rejections under 35 U.S.C. 112, second paragraph, are withdrawn in view of Applicant's arguments.

The previous rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) not reiterated below are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are addressed following the rejections necessitated by the amendments.

Claims 1-6 are under prosecution.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1 and 3-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al (U.S. Patent No. 5,922,617, issued 13 July 1999).

The following rejections are maintained from the previous Office Action.

Regarding claim 1, Wang et al teach a bioassay substrate in the form of the disc-shaped bioassay substrate of Figure 6, which is equally divided into 4 sectors 82 (column 14, line 60-column 15, line 10). The substrate further comprises optically interpretable recorded information in the form of header 86 (column 14, line 60-column 15, line 10). The disc further comprises a plurality of detection units comprising a data detecting area comprising a reaction area for performing a mutual reaction process between substances to be detected and a target substance; namely, Figure 6 shows the track 84 in each area 82, wherein the track comprises a bound component therein (column 6, lines 15-45), wherein the bound component is a nucleic acid (Figure 1A and column 3, lines 10-35). The area of the track comprising the area between the immobilized nucleic acids is the claimed reaction area (Figures 5 and 6). The data detecting area further comprises a detection surface for fixing end portions of the substances to be detected; namely, the tracks (i.e., grooves) have walls (i.e., sides; column 8, lines 10-45). The data detection area has a first length in a radial direction; namely, Figure 5 shows segments 70 wherein nucleic acids can be located (column 15, lines 35-60). The distance between each pair of track marks is the length in the radial direction.

It is noted that the courts have held that "while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function." *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). In addition, "[A]pparatus claims cover what a device *is*, not what a device *does*." *Hewlett-*

*Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). The claim requires "a detection surface for fixing end portions of the substances to be detected" wherein "the detection surface being formed at a side of the data-detecting area." The claim therefore only requires an area "for fixing," and does not actually require substances to be fixed to the area. Thus, the limitation "a detection surface for fixing end portions of the substances to be detected" wherein "the detection surface being formed at a side of the data detecting area" merely recites an intended use of the detection surface and an intended use of the side of the data detecting area (i.e., the walls of the grooves). Because the various uses recited above fail to define additional structural elements of the claimed substrate, the claim is anticipated by Wang et al. See MPEP § 2114.

Wang et al further teach a servo are formed in the detection unit without overlapping the data detecting area; namely, the servo area comprises the areas within the track comprising the header marks 86, which are separate from and non-overlapping with data detecting area (Figures 5-6). The header marks optically provide information on the data detecting area; namely, the sector and track number (column 14, line 60-column 15, line 10). The servo area has a first length in a radial direction; namely, Figure 6 shows header marks 86 each aligned within a track. The radial distance with track marks is the length in the radial direction, which is approximately equal to the radial length for the data detect because both the header and the particles are within the same track (Figure 6).

Regarding claim 3, Wang et al teach the substrate of claim 1.

As noted above, the courts have held that apparatus claims cover what a device *is*, not what a device *does*. Claim 3 is drawn to the substances to be detected, the target substance, and the mutual reaction process, which is clearly a recitation of intended use of the claimed substrate. In addition, while independent claim 1 is drawn to as substrate “for performing a mutual reaction process between substances to be detected and a target substance,” neither claim 1 nor claim 3 actually requires the substances to be detected, or the target substances (i.e., as detailed above in the rejection of claim 1). Thus, claim 3 is entirely a recitation of the intended use of the claimed substrate and does not require any further structural limitations of the claimed substrate. Because Wang et al teach all of the structural elements of the claim, the claim is anticipated by Wang et al.

Regarding claim 4, Wang et al teach the substrate of claim 1 wherein the detection units are arrayed along the circumferential direction (Figure 5).

Regarding claim 5, Wang et al teach the substrate of claim 1 wherein the detection units are arrayed in concentric circles or spiral shapes; namely, the concentric tracks of Figure 6.

Regarding claim 6, the substrate of claim 1 is discussed above. Wang et al also teach the positional information comprises a tracking mark and an address mark; namely, the header marks optically provide the sector (i.e., address) and track number (column 14, line 60-column 15, line 10).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The following are new rejections necessitated by the amendments.
6. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al (U.S. Patent No. 5,922,617, issued 13 July 1999) in view of Okano et al (U.S. Patent No. 6,183,970 B1, issued 6 February 2001).

It is noted that while claims 1 and 3-6 have been rejected under 35 U.S.C 102(b) as described above in Section 3, the claims are also obvious using the alternative interpretation outlined below.

Regarding claims 1-2, Wang et al teach a bioassay substrate in the form of the disc-shaped bioassay substrate of Figure 6, which is equally divided into 4 sectors 82 (column 14, line 60-column 15, line 10). The substrate further comprises optically interpretable recorded information in the form of header 86 (column 14, line 60-column 15, line 10). The disc further comprises a plurality of detection units comprising a data detecting area comprising a reaction area for performing a mutual reaction process between substances to be detected and a target substance; namely, Figure 6 shows the track 84 in each area 82, wherein the track comprises a bound component therein (column 6, lines 15-45), wherein the bound component is a nucleic acid (Figure 1A and

column 3, lines 10-35). The area of the track comprising the area between the immobilized nucleic acids is the claimed reaction area (Figures 5 and 6). The data detecting area further comprises a detection surface for fixing end portions of the substances to be detected in the form the area of the track to which the particles bearing the nucleic acids are attached (Figures 2C and 2D). The data detection area has a first length in a radial direction; namely, Figures 5 and 6 show the particles confined to track. The distance between each pair of track marks is the length in the radial direction.

It is noted that the claim requires "a detection surface for fixing end portions of the substances to be detected." The claim therefore only requires an area for fixing, and does not actually require substances to be fixed to the area. Thus, the limitation "a detection surface for fixing end portions of the substances to be detected" merely recites an intended use of the detection surface.

Wang et al further teach a servo are formed in the detection unit without overlapping the data detecting area; namely, the servo area comprises the areas within the track comprising the header marks 86, which are separate from and non-overlapping with data detecting area (Figures 5-6). The header marks optically provide information on the data detecting area; namely, the sector and track number (column 14, line 60-column 15, line 10). The servo area has a first length in a radial direction; namely, Figure 6 shows header marks 86 each aligned within a track. The radial distance with track marks is the length in the radial direction, which is approximately



equal to the radial length for the data detect because both the header and the particles are within the same track (Figure 6).

While Wang et al teach solid support is prepared for attachment of components (i.e., particles; column 2, lines 1-15), Wang et al do not explicitly teach a detection surface formed at a side of a data- detecting area (i.e., claim 1) that included a surface treatment to detect the substances (i.e., claim 2).

However, Okano et al teach a data-detecting area of a bioassay substrate in the form of a polynucleotide probe chip (Figures 1A-B), having data-detecting areas in the form of holes (column 6, lines 25-45). The surface of the side of the data-detecting area is a detection surface is treated to fix substances; namely, polynucleotide probes 34 are fixed onto gels in the holes, wherein the gel is fixed on the side 21 of the hole (i.e., claim 1; Figure 3 and column 8, lines 1-20). The gel immobilized on the side of the data-detecting area is the surface treatment of the side of the data-detecting area (i.e., claim 2). Okano et al also teach the side surface treatment (i.e., gel) has the added advantage of improving the kinetics of the hybridization to a sample polynucleotide (column 2, lines 45-55). Thus, Okano et al teach the known technique of using a surface treatment on the side of the data-detecting area to fix substances thereon (i.e., claim 1-2).

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the substrate as taught by Wang et al so that the immobilized substance is immobilized on the side of the data detecting area (i.e., claim 1) on a detection surface that includes a surface treatment (i.e., claim 2)

as taught by Okano et al to arrive at the instantly claimed substrate with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a substrate having the added advantage improving the kinetics of the hybridization to a sample polynucleotide as explicitly taught by Okano et al (column 2, lines 45-55). In addition, it would have been obvious to the ordinary artisan that the known technique of using a surface treatment on the side of the data-detecting area to fix substances thereon as taught by Okano et al could have been applied to the substrate of Wang et al with predictable results because the known technique of using a surface treatment on the side of the data-detecting area to fix substances thereon as taught by Okano et al predictably results in a reliable arrangement for immobilization and detection of probes.

Regarding claim 3, the substrate of claim 1 is discussed above. Wang et al teach the substances to be detected and the target substances are nucleotides (Figure 1A and column 3, lines 10-35) and the mutual reaction process is hybridization (column 4, lines 10-35).

Regarding claim 4, the substrate of claim 1 is discussed above. Wang et al also teach the detection units are arrayed along the circumferential direction (Figures 5-6).

Regarding claim 5, the substrate of claim 1 is discussed above. Wang et al further teach the detection units are arrayed in concentric circles or spiral shapes; namely, the concentric tracks of Figure 6.

Regarding claim 6, the substrate of claim 1 is discussed above. Wang et al teach the positional information comprises a tracking mark and an address mark;

namely, the header marks optically provide the sector (i.e., address) and track number (column 14, line 60-column 15, line 10).

### ***Response to Arguments***

7. Applicant's arguments filed 12 March 2009 (hereafter the "Remarks") have been fully considered but they are not persuasive for the reason(s) listed below.

A. With respect to the rejection of claim 5 under 35 USC 112, second paragraph, Applicant's arguments on pages 5-6 of the Remarks have been fully considered and are persuasive. The rejection of claim 5 under 35 USC 112, second paragraph has been withdrawn.

B. Applicant argues on pages 6-7 of the Remarks that Wang et al does not teach a coat that is formed at a side of the grooves, and thus does not teach "the detection surface being formed at a side of the data-detecting area" as required by claim 1.

However, as noted above, the claim requires "a detection surface for fixing end portions of the substances to be detected" wherein "the detection surface being formed at a side of the data-detecting area." The claim therefore only requires an area "for fixing," and does not actually require substances to be fixed to the area. Thus, the limitation "a detection surface for fixing end portions of the substances to be detected" wherein "the detection surface being formed at a side of the data detecting area" merely recites an intended use of the detection surface and an intended use of the side of the data detecting area (i.e., the walls of the grooves). Because the various uses recited

above (i.e., having a side that can have portions of substances fixed thereon) fail to define additional structural elements of the claimed substrate, the claim is anticipated by Wang et al.

C. Applicant's arguments with respect to the previous rejection of claims 1-6 as obvious over Iwasaki et al in view of Wang et al have been considered but are moot in view of the new ground(s) of rejection necessitated by the amendments.

### ***Conclusion***

8. No claim is allowed.
9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
10. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571)272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert T. Crow/  
Examiner, Art Unit 1634

Robert T. Crow  
Examiner  
Art Unit 1634

/JD Schultz/

Supervisory Patent Examiner, Art Unit 1635